



GP 1815

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GRUENBERG

Serial No.: 08/700,565

Filed: July 25, 1996

For: AUTOLOGOUS IMMUNE CELL THERAPY;  
CELL COMPOSITIONS, METHODS AND  
APPLICATIONS TO TREATMENT OF  
HUMAN DISEASE

Art Unit: 1815

Examiner: Schwadron, R.

I hereby certify that this paper and the attached papers are being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents,  
Washington, D.C. 20231, on this date.

08/19/97

Date

*[Handwritten signature]*  
Stephanie Seidman

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**SEP 10 1997**

**GROUP 1800**

**ELECTION**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Responsive to the Requirement for Restriction, mailed July 22, 1997, applicant elects Group I, claims 1-17 and 22-35, with traverse, for examination on the merits.

**REMARKS**

Any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 02-4070. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

**Requirement for Restriction between group II and group III**

Applicant traverses the restriction requirement as between group II, claims 36-41, which is directed to methods of making virally purged CD4<sup>+</sup> cells, and group III, which includes claims, such as claims 43 and 150, which directed to compositions produced by the methods of comprising virally purged CD4<sup>+</sup> cells produced by the method of claim 36 and 41, respectively. For restriction to be proper, the subject matter of the claims must be independent or distinct. In this instance, the subject matter is neither independent nor distinct.

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The subject matter of group II and group III are related a process of making a product made. In this instance, as between group II and claims 43 and 150, the product **as claimed** cannot be made by another materially different process, since the claim specifically requires that the product is made by a process of group I. Furthermore, the process, which a process of making compositions of virally purged cells cannot be used to make another materially different product. Therefore, as between groups I and claims 43 and 150 even one-way distinctness cannot be shown. Thus, restriction is improper.

In addition, if claims 43 and 150 are included in group II, as they should be, then group II and the remaining claims in group III are not distinct because both groups include compositions that neither independent nor distinct. If the claims are restricted into these two groups, applicant ultimately could be granted two patents, that include claims encompassing compositions containing virally purged CD4+ cells that could (in the event of appeal, other extension, or a change in the present measure of the patent term) expire on different dates. Applicant could, thus, obtain two patents directed to virally purged CD4+ cells and thereby extend patent coverage. Obvious-type double patenting of claims of the later issuing patent could not be held over the earlier issuing patent. See MPEP 806, paragraph 3, which states:

[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Since, if restriction is required by the Office double patenting cannot be held, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

35 U.S.C.121, third sentence, provides that wherein the Office requires restriction, the patent of either the parent or any divisional application thereof conforming to the requirement cannot be used as a reference against the other. This apparent nullification of double patenting as ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same inventions in different language and


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which, if acquiesced in, might result in the issuance of several patents for the same invention.

Therefore, reconsideration and withdrawal of the restriction requirement as between groups I and group II are, therefore, respectfully requested.

\* \* \*

Respectfully submitted,  
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